



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

FEB -3 1999

Re: LIPOSORBER® LA-15  
Docket No. 96E-0189

Stephen G. Kunin  
Deputy Assistant Commissioner for  
Patent Policy and Projects  
Office of the Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Crystal Park Building 2, Suite 919  
Washington, DC 20231

Dear Mr. Kunin:

This is in regard to the patent term extension application for U.S. Patent No. 4,637,994 filed by Kanegafuchi Kagaku Kogyo Kabushiki Kaisha under 35 U.S.C. § 156. The patent claims the medical device LIPOSORBER® LA-15 (angio-seal\* hemostatic puncture), premarket approval application PMA P880019.

In the May 4, 1998, issue of the Federal Register (63 Fed. Reg. 24557), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before November 2, 1998, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs

cc: Louis Gubinsky  
Sughrue, Mion, Zinn, MacPeak & Seas  
2100 Pennsylvania Ave., NW  
Washington, DC 20037-3202

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